DEC 0 6 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K013027

1. Submitter's Identification:

Respironics HealthScan, Inc.
41 Canfield, Road
Cedar Grove, NJ 07009

Contact: Ms. Lauren R. Ziegler, Senior Manager, Technical Services

Date Summary Prepared: August 8, 2001

2. Name of the Device:

Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123

3. Predicate Device Information:

InvaCare Envoy Jr., K# 914251

4. Device Description:

This line-powered piston compressor is housed in a plastic cabinet (case). Dimensions are 7.3 in. x 6.9 in. x 4.0 in. and weighs 3.3 lbs. It consists of a motor-driven piston compressor, an in-line fuse, and a switch; it contains no microprocessors or other electronic components. It operates from 115 VAC, 60 Hz. It is supplied with tubing, an instruction manual, and a 510(k) cleared nebulizer.

In use, the compressor is placed on a flat surface and the nebulizer tubing is connected to the hose barb. The unit is then turned on. Inlet air to the compressor passes through a replaceable filter.

5. Intended Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care.

This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, COPD, etc.

6. Comparison to Predicate Devices:

The subject (Mister Neb™) and predicate device (InvaCare Envoy Jr., K#914251) are indicated for the same intended use, are AC-powered, meet Environmental Safety and EMC requirements, and have similar compressor operating pressure and flow ranges. Performance characteristics are basically the same, and both units are lightweight.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following Environmental and Safety Testing was conducted:

Testing information demonstrating safety and effectiveness of the Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. Maximum pressure and flow under all combinations of the following:
   - Temperatures of $+5^0$ and $+20^0$C, and 40^0C with 95% RH:
   - Line voltage of 95, 115, and 132 V

b. Storage at -20^0C and at $+60^0$C
c. Fluid spill resistance
d. Surface and air temperatures
e. Sinusoidal vibration
f. Impact (drop) resistance
g. Leakage current and dielectric withstand (electrical safety)

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123, device sample(s) tested met all relevant requirements of the aforementioned test.

In addition, the following EMC testing was conducted:

a. Radiated and Conducted Emission per CISPR 11

b. Magnetic Field Emission per MIL-STD-462D, Method RE101
c. Fast surges per Reviewer Guidance document

Because the compressor contains no electronic components (e.g., microprocessors), the radiated and conducted immunity tests were not applicable. The device was tested as described in the EMC Testing Results to simulate, as closely as possible, actual operating conditions.

The device tested met the EMC criteria recommended by the FDA

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123 is as safe and effective as predicate devices presently on the market, based on electrical, mechanical, environmental and EMC testing results outlined in the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions". We also adhered to FDA's DCRND "Reviewer Guidance for Home Use Respiratory Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Respironics HealthScan, Inc.
c/o Mr. Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K013027
Mister Neb™ Nebulizer Compressor, Model HS123
Regulation Number: 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: Class II (two)
Product Code: BTI
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

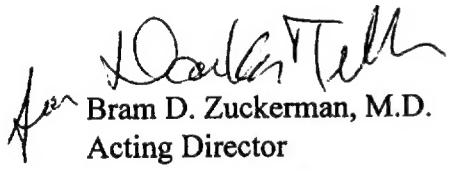
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K013027

Device Name: Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123

Indications For Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma, allergies, COPD, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013027

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**